

### Remarks

The Office Action mailed January 13, 2003 has been received and reviewed. Claims 6 through 11, 14, 17 and 18 are pending. Claims 6 through 8, 10, 11, 14, 17 and 18 are rejected, claim 9 is objected to. Applicants have canceled claim 6 without prejudice or disclaimer and reserve the right to pursue such claim in a related application. Applicants have amended claims 7 and 14, and added new claim 19. Reconsideration of the application as amended is respectfully requested.

Applicants note that the objection to claim 14 and the rejection of claims 14 and 18 under 35 U.S.C. § 102(b) have been withdrawn. The attention of the Examiner to the application is appreciated. The remaining and newly presented rejections are addressed below.

### 35 U.S.C. § 102 Rejections

The rejection of claim 6 as assertedly anticipated by Allen-Vercos et al. under 35 U.S.C. § 102(b) was maintained from the prior Office Action. Claim 6 has been canceled herein rendering this rejection moot.

The rejection of claims 6-8 and 10-11 as assertedly anticipated by WO 89/10967 to Marjarian et al. (hereinafter "Marjarian") under 35 U.S.C. § 102(b) was maintained from the prior Office Action. Claim 6 has been canceled herein rendering this rejection moot as to it. Applicants respectfully submit that amended claim 7, and the claims dependent therefrom, define over Marjarian.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Office Action states that applicants' remarks in the prior Amendment were not persuasive as it "is the Examiner's position that Applicant appears to argue limitations that are not in the claims." Specifically, the Office Action states that there is "no requirement in the claims that the claimed vaccines should be minus bacteria." (Office Action at page 6).

As amended, independent claim 7 reads:

A vaccine for the protection of animals against Salmonellosis, **comprising an immunologically effective amount of a mutated bacterium and a pharmaceutically acceptable carrier**, said mutated bacterium being selected from the group consisting of the *Salmonella* species *typhimurium*, *enteritidis*, *choleraesuis*, *dublin*, *abortus-ovi*, *abortus-equi*, *derby*, *hadar*, *heidelberg*, *agona*, and *arizonae*, that in its wild type form carries flagella, **said mutated bacterium lacking flagellin**. (Emphasis added).

Applicants respectfully submit that amended claim 7 thus includes elements not disclosed in Marjarian, including a vaccine comprising an immunologically effective amount of a mutated bacterium lacking flagellin. Accordingly, it is requested that this rejection be withdrawn and amended claim 7, with the claims dependent therefrom, be allowed.

The rejection of claims 14 and 17-18 as assertedly anticipated by Marjarian under 35 U.S.C. § 102(b) was maintained from the prior Office Action. Applicants respectfully submit that as amended, claim 14, with claims 17 and 18 dependent therefrom, defines over Marjarian.

As with the rejection of claims 7-8 and 10-11, the Office Action states that applicants' remarks' in the prior Amendment were not persuasive as it "is the Examiner's position that Applicant appears to argue limitations that are not in the claims." Specifically, the Office Action states that there is "no requirement in the claims that the flagellin gene in the mutated bacterium used in the claimed vaccines be absent" or "that the claimed vaccines should be minus bacteria." (Office Action at pages 8-9).

As amended, independent claim 14 reads:

A live attenuated vaccine for the protection of a subject against Salmonellosis comprising **an immunologically effective amount of a mutated bacterium** and a pharmaceutically acceptable carrier, said mutated bacterium being **selected from the group consisting of the *Salmonella* species *typhi* and *paratyphi A* and *B***, that in its wildtype form carries flagella, **said mutated bacterium lacking flagellin**. (Emphasis added).

The Office Action states that 'with the disclosure of subunit vaccines that comprise recombinant flagellin fusion proteins, Marjarian et al teach vaccines that are minus bacteria and do not require the gene be present.' (Office Action at page 9). In the same section, Marjarian page 45 is cited as disclosing the recombinant flagellin fusion protein vaccines for use in subunit vaccines. An examination of this section of Marjarian, on pages 45-45 thereof, reveals that it is directed to the

harvesting of recombinant flagellin from a bacterium by containing flagella by "mechanical means which do not otherwise damage the cell" followed by processing of such harvested recombinant flagellin into a subunit vaccine. There is no teaching of vaccines "that are minus bacteria and do not require the gene be present." Further, the flagellin minus bacteria disclosed in Marjarian as useful for expressing the recombinant flagellin epitopes were obtained from "an aromatic dependent S. dublin parent strain" (Marjarian at page 49). None of *Salmonella* species *typhi* and *paratyphi A* and *B* with the required features are disclosed in Marjarian.

Accordingly, Applicants respectfully submit that amended claim 14 thus includes elements not disclosed in Marjarian and it is requested that this rejection be withdrawn and amended claim 14, with claims 17 and 18 dependent therefrom, be allowed.

### **35 U.S.C. § 112 Rejections**

Claim 7 was rejected in the Office Action as assertedly lacking enablement under 35 U.S.C. §112, first paragraph. The Office Action states that the specification while "enabling for a mutated bacterium does not reasonably provide enablement for antigenic material thereof." (Office Action at page 10). While applicants do not agree, claim 7 has been amended to be directed to a vaccine "comprising an immunologically effective amount of a mutated bacterium" and no longer includes the language "or antigenic material thereof." Accordingly, it is respectfully submitted that claim 7, as amended, is fully enabled. Applicants request this rejection be withdrawn and amended claim 7 be allowed.

Similarly, claim 14 was rejected in the Office Action as assertedly lacking enablement under 35 U.S.C. §112, first paragraph. The Office Action states that the specification while "enabling for a mutated bacterium does not reasonably provide enablement for antigenic material thereof" (Office Action at page 11). The Office Action then goes on to discuss the language "mutagenic material" and concludes that such language is lacking enablement. While applicants do not agree, claim 14 has been amended to be directed to a vaccine "comprising an immunologically effective amount of a mutated bacterium" and no longer includes the language "or mutagenic material thereof." Applicants respectfully submit that amended claim 14 is fully enabled and request it be allowed.

Claim 7 was rejected in the Office Action as assertedly "failing to particularly point out and distinctly claim" the subject matter under 35 U.S.C. §112, second paragraph. The Office Action cites the language "antigenic material" as assertedly unclear. As previously stated, claim 7 has been amended to no longer include this language and it is respectfully requested that the rejection be withdrawn.

Claim 14 was also rejected in the Office Action as assertedly "failing to particularly point out and distinctly claim" the subject matter under 35 U.S.C. §112, second paragraph. The Office Action cites the language "mutagenic material" as assertedly unclear. As previously stated, claim 14 has been amended to no longer include this language and it is respectfully requested that the rejection be withdrawn.


#### **New Claim**

At page 10 of the Office Action, claim 9 is objected to as being dependent upon an rejected base claim, but was noted to "be allowable if rewritten in independent form including all the limitations of the base claim...." New claim 19 presents claim 9 rewritten in independent form and including limitations from prior claim 7, from which claim 9 depended. Accordingly, it is requested that new claim 19 be allowed.

## CONCLUSION

All pending claims are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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**VERSION WITH MARKINGS SHOWING CHANGES MADE  
IN THE CLAIMS:**

Please amend the remaining claims as follows:

7. (Three Times Amended) A vaccine for the protection of animals against Salmonellosis, comprising an immunologically effective amount of a mutated bacterium [or antigenic material thereof] and a pharmaceutically acceptable carrier, said mutated bacterium being selected from the group consisting of the *Salmonella* species *typhimurium*, *enteritidis*, *choleraesuis*, *dublin*, *abortus-ovi*, *abortus-equi*, *derby*, *hadar*, *heidelberg*, *agona*, and *arizonae*, that in its wild type form carries flagella, said mutated bacterium lacking [at least one antigenic determinant of] flagellin [or flagella found in its wild type form].

14. (Two Times Amended) A live attenuated vaccine for the protection of a subject against Salmonellosis comprising an immunologically effective amount of a mutated bacterium [or mutagenic material thereof] and a pharmaceutically acceptable carrier, said mutated bacterium being selected from the group consisting of the *Salmonella* species *typhi* and *paratyphi A* and *B*, that in its wildtype form carries flagella, said mutated bacterium lacking [at least one antigenic determinant of] flagellin [or flagella found in its wildtype form].